

In the Claims:

Please cancel claims 27-30. ✓

REMARKS

1. Claims 20-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson in view of Sanders.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2142.

The present invention is directed to a method of detecting the presence of urinary pathogens in a biological sample and of simultaneously determining the susceptibility of the pathogens to various antimicrobial agents. The present invention accomplishes this, as recited in Claim 20, by providing "a multicompartment assay device comprising at least one compartment comprising a medium capable of sustaining the growth of total microbial organisms; at least one compartment comprising a uropathogenic specific medium; and at least one compartment comprising an antimicrobial susceptibility interpretation medium."

The specification defines "uropathogenic specific medium" at page 12 as "a medium which allows only the growth of the primary urinary gram negative pathogens and allows for substantially less growth of any other bacteria of a biological matrix." The specification defines "primary gram negative urinary pathogen" at page 10 as "the group of bacteria which cause at least 85-90% of the human and veterinary urinary tract infections. These include but are not limited to: *Escherichia coli*, *Klebsiella spp.*, *Enterobacter spp.*, and *Proteus mirabilis*." Therefore, the present claims incorporate the limitation of a medium which selects for primary gram negative urinary pathogens, as defined above. Nowhere in the prior art is there taught or suggested a growth medium which is capable of selecting for primary gram negative urinary pathogens.

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Johnson discloses a device for use in exposing a test sample to a variety of antibiotics and for determining the susceptibility of microorganisms to those antibiotics. Johnson completely fails to disclose a growth medium capable of selecting for primary gram negative uropathogens, as recited in the present claims. In fact, Johnson discloses no particular media at all, only that media are to be used in the invention. The device of Johnson functions by introducing bacteria into the individual wells which are charged with dried growth medium; and in some cases, antibiotics in addition to the growth medium.

Thus, Johnson in no way discloses the invention of the present claims which recite a medium which selects for the primary gram negative uropathogens.

The Examiner specifically points to Col. 3, lines 31-36 of Johnson stating "Johnson further teaches that his method and device may be used to analyze urinary pathogens, specifically *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella*, *Enterobacter*, *Proteus spp.*, *Enterococcus*, and *Staphylococcus aureus*" (page 7, Office Action of 4/28/99). Relying on Johnson and other available prior art, this is possible only by individually isolating colonies from a urine specimen, and analyzing them individually in the device because neither Johnson, nor any other cited reference discloses a medium which is capable of selecting for primary gram negative uropathogens, as disclosed in the specification of the present invention and recited in the claims.

In contrast to the device of Johnson, the present invention operates by introducing a biological sample directly into the compartments of the device of the present invention which contain the three media: a total growth medium, a uropathogen-specific medium, and a microbial susceptibility medium. The specific medium of the present invention selects for primary gram negative uropathogens (those organisms responsible for at least 85-90% of human and veterinary urinary tract infections,

as defined on page 10 of the specification), and only these organisms grow in this medium. No preliminary growth step is required because the medium of the present invention selects for the primary gram negative uropathogens.

In view of the foregoing, the Applicants respectfully request that the rejection be withdrawn and that the claims be passed to allowance.

2. Claims 20 and 26 are rejected under 35 U.S.C § 103(a) as being unpatentable over Johnson in view of Sanders as applied to claim 20 above, and further in view of Brocco.

The Examiner asserts that Brocco "teaches a method of determining susceptibility of uropathogens, specifically Staphylococcus and Streptococcus, to amoxicillin and a clavulanic acid mixture" (page 9, Office Action of 4/28/99). Staphylococcus and Streptococcus are gram positive bacteria. They are most frequently encountered as normal urethral contaminants (See specification, page 1, lines 25-28). Brocco in no way defeats the patentability of the present claims which comprise a "uropathogenic specific medium" which allows only the growth of primary urinary GRAM NEGATIVE pathogens (See definition, page 12 of the specification). Staphylococcus and Streptococcus are not selected for in the uropathogenic specific medium of the present claims.

Like Johnson and Sanders, Brocco completely fails to teach or suggest a uropathogenic specific medium as recited in the present claims and defined on page 12 of the specification.

Therefore Brocco alone or in combination with any of Johnson or Sanders, does not teach or suggest the presently claimed invention. Consequently, the presently claimed invention is not obvious over Johnson in view of Sanders and Brocco.

These amendments and remarks clarify the present invention, and withdrawal of the rejection is requested.

#### Conclusion

In view of the above, the Applicants submit that the claims are in condition for allowance. The Applicants respectfully request that they be allowed and passed to issue.

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Respectfully submitted,  
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